



PATENT

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#12
JRP
9/25/92

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of) Group Art Unit: 1205
5 GEORGE A. BROOKS) Examiner: R. HENLEY III
Serial No. 07/471,287)
10 Filed: January 26, 1990) DECLARATION OF
For: METHOD AND COMPOSITION) GEORGE A. BROOKS
FOR NUTRITIONAL) UNDER 37 C.F.R. § 1.132
SUPPLEMENTATION DURING)
EXERCISE AND RECOVERY) 2001 Ferry Building
San Francisco, CA 94111
(415) 433-4150
)

15 Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

20 I, George A. Brooks, do hereby declare and state
that:

25 1. I am the sole inventor in the above
referenced patent application. I have conducted
and/or supervised a considerable amount of scientific
research in the field of exercise physiology. My
curriculum vitae is attached as Exhibit A.

2. I have reviewed the Kober reference which
was cited against the claims in the above referenced
patent application. The below comments address the
teachings of this reference as compared to the
invention claimed in the instant application. My
below comments also provide a general discussion of
the conventional wisdom in the art concerning lactic
acid and its effects in exercise physiology.

3. The Kober patent is directed to a food
composition that is rich in minerals, and contains
lactate as a stabilizing agent. Depending on whether

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GROUP 12

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with
the United States Postal Service as First Class
mail, addressed to: Commissioner of Patents
Washington, DC 20231 on September 10, 1992
By George A. Brooks

one follows the wet formulation (lines 24-46) or dry formulation (lines 112-115) of Kober, the resulting solution will have a mineral salt concentration ranging from 11-20%. Such a salt concentration is 5 far too high to benefit fluid, electrolyte or carbohydrate balance during exercise and/or recovery.

4. As provided in Table 12-2 from Eckert, Randall and Augustine, Animal Physiology Mechanisms and Adaptation, Third Edition (Exhibit B), sea water 10 contains 460 and 540 mOsmole of sodium and chloride, respectively. Thus, at 540mM, the NaCL content of sea water would approximate 31 g/l or 3.1%. In effect, the consumption of Kober's mineral salt 15 solution would be worse for the dehydrated athlete than consumption of sea water.

5. For comparison, human plasma concentration is approximately 304 mOsmol, of which 142 mOsmol is from sodium, and 104 mOsmol is from chloride. Because of the relatively high NaCl content of 20 plasma, normal saline for intravenous infusion contains 155 mEq each of Na⁺ and Cl⁻, yielding a total NaCl content of 310 mEq (0.9g NaCl per 100ml water, or 0.9%).

6. Thus, Kober's solutions tend to be a full 25 order of magnitude greater in salt concentration than normal saline solutions used for intravenous infusion. In contrast to plasma at 0.9%, the sodium content of sweat is quite small (18 mEq per liter, or 0.05%). The salinity of human plasma rises during 30 exercise because fluids are lost while mineral salts remain in the plasma. For these reasons, salinity of fluid electrolyte replacement beverages typically reflect sweat losses, rather than plasma content. For

example, in the instant application, 0.2% sodium lactate is used to replenish sodium losses during exercise.

7. For many years, the conventional wisdom in the art of exercise physiology was that muscle fatigue was caused by accumulation of lactic acid. Therefore, carbohydrate nutrient compositions having either lactic acid or lactate salts as a nutritional component were not considered beneficial to the exercising athlete because it was believed that additional lactates would accelerate fatigue.

10 Therefore, conventional thought on lactic acid taught away from the use of lactates as a nutritional supplement for exercising athletes. The relevant portions of several textbook references, which date from 1932 to 1986, attached hereto (Exhibit C) demonstrate the conventional wisdom on lactic acid fatigue.

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8. More recently, beneficial metabolic effects of lactate have been identified. An example of this beneficial effect is reported in the textbook reference attached as Exhibit D. However, even the more recent scientific literature does not disclose or suggest the concept of using lactic acid salts as a carbohydrate nutritional supplemental. This concept was not known prior to the instant invention.

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9. I further declare, under penalty of perjury under the laws of the United States of America, that all statements made herein of my own knowledge are true and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both,

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under Section 1001 of Title 18 of the United States
Code.

Dated:

9/4/92

George A. Brooks

